



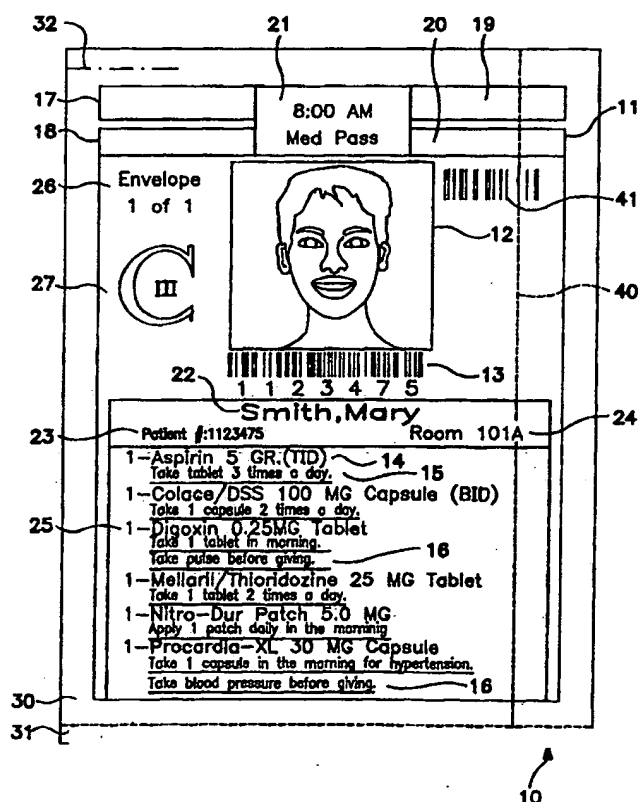
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: G06F 17/00, A61J 1/00	A1	(11) International Publication Number: WO 99/17218 (43) International Publication Date: 8 April 1999 (08.04.99)
(21) International Application Number: PCT/US98/20550 (22) International Filing Date: 30 September 1998 (30.09.98) (30) Priority Data: 60/060,646 1 October 1997 (01.10.97) US (71)(72) Applicant and Inventor: CLONINGER, Timothy, N. [US/US]; 1092 Gannon Court, Hoffman Estates, IL 60194 (US). (74) Agents: SILVERMAN, Howard, E. et al.; Law Offices of Dick and Harris, Suite 3800, 181 W. Madison Street, Chicago, IL 60602 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: A CONTAINER FOR PREVENTING ERRORS IN THE DISPENSING OF PHARMACEUTICALS TO PATIENTS IN A HEALTH CARE ENVIRONMENT

(57) Abstract

An apparatus is disclosed for containing medications to be dispensed to patients in a manner so as to minimize error which includes a container (10) for holding medications to be dispensed to a patient and a label associated with the container (10) having a photographic likeness (12) of the patient who is the intended recipient of the medications held in the container, as well as other indicia pertaining to the patient, and the number, type, dose and delivery time pertaining to medications to be dispensed. The individual dispensing the medication is thus provided with a visual cue to be able to compare the patient to whom the medication is being given with a photographic likeness to permit the individual to quickly and accurately verify that the medication is being given to the proper patient.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

TITLE OF THE INVENTION

A CONTAINER FOR PREVENTING ERRORS IN THE DISPENSING OF
PHARMACEUTICALS TO PATIENTS IN A HEALTH CARE ENVIRONMENT

BACKGROUND OF THE INVENTION

1. The Technical Field

The invention is directed to a method and apparatus for preventing errors from occurring during the process of dispensing medications and pharmaceuticals to patients in a hospital, or other in-patient health care environment. The present invention may have further application in a retail pharmacy environment, as well as in non-medical environments. For example, the invention may have application in virtually any industry or environment where a correspondence between a given object and its intended recipient or use is critical. The apparatus of the present invention may, for example, also be used to control the dispensing and use of critical safety-related parts for machines, such as aircraft engines, where use of an incorrect part may cause catastrophic equipment failure and consequential injury or loss-of-life.

2. Background

In its principle embodiment, the invention is designed to help prevent individuals who are dispensing medications to hospital patients from making mistakes when delivering or dispensing such medications.

In a hospital, or similar health care facility, medications and pharmaceuticals are typically stored in a central in-house pharmacy. Pharmacists, or other health care technicians, generally prepare the various doctor ordered medications on a patient-by-patient basis by manually selecting the medications from their storage containers or bins and assembling a collection of medications to be dispensed to the patient. Typically, a doctor orders prescribe that one or more medications be given to a patient at prescribed frequency over a particular period of time. For example, a doctor may

order that a particular medication in a particular dose be dispensed to the patient every six hours for three consecutive days. In many hospital environments the hospital pharmacy will assemble the prescribed doses for the patient for a period of time, such as a complete nursing shift, during which shift the patient in the above example may receive two doses of the medication.

Typically the medications ordered by doctors are placed by the pharmacist and/or technician into individual medication trays, one for each patient. The trays are in turn placed into a cassette which is in turn placed into a medication cart, which is wheeled through the hospital to each patients' room, where the medications are ultimately delivered to the patients. The empty medication cassettes are returned to the pharmacy for refilling. The trays typically contain visual information which identify which patient is to receive the medication in the tray and may further contain information which identifies the actual medications themselves.

With increasing availability of robotic technology and computer control a growing trend is to automate the selection of medications and filling of the medication trays by use of a computer controlled robot which selects unit dose pre-packaged medications from a storage area and places them in the medication tray, which is in turn placed in the medication cart.

Both the described "manual" and "automated" systems nevertheless present many opportunities for error to occur resulting in the wrong medication being delivered, medications being delivered to the wrong patient, the wrong dose or form of medications being delivered, the proper medication is given to the intended patient but at the wrong time, or delivery of medications being missed.

Mistakes are often made at the time when the medications are to be actually dispensed to the intended patients often because the individuals charged with the responsibility are often rushed, or the medications to be dispensed are not well organized. The individual dispensing the medication is often under time pressure or has to deal with a large volume of similar looking medications when choosing the specific medication to be given to the patients and often does not have time, or take the time, to read the orders or instructions to insure that the proper quantities that are to be

dispensed. In a large health care setting the sheer number of patients and the associated number of medications to be delivered create an environment in which error is likely to occur. These reasons, among other reasons, will often lead to items being given in error which can of course injure or even kill patients. It is believed that the error rate in delivering pre-packaged unit dose medications in a health care setting may be as high as 5% percent and is believed to be even higher when delivering non-unit dose medications. In practice, the nurse dispensing medication to a patient must retrieve the medication, typically from a medication cart which is either rolled from room to room or kept stationary at a nursing station. The nurse typically reads a patient chart to determine which medications are to be given at that hour and retrieves those medications from a tray in the cart assigned to the patient. The tray contains all of the medications for the patient which are to be dispensed over the period of time during which that particular medication cart is in use. For example, the cart may be refilled for each nursing shift. In an eight hour nursing shift an individual patient may however receive multiple doses of a multiple medications -- but at different times as well as a single dose of a particular medication at a single time during the shift. The nurse must accurately read the proper patient's chart and must accurately select the proper medications from the proper medication tray and dispense the proper medications at the proper time to the proper patient.

In addition to giving the wrong medication to a patient, errors include giving the proper medication to a patient at the wrong time (8:00 AM instead of 10:00 AM); giving the proper medication on the wrong day (Monday instead of Tuesday) giving the medication using the wrong method (an injection into a patient instead of giving orally); giving the wrong form of the medication (a liquid versus a solid form); giving the medication to the wrong patient, or not giving the intended patient any medication at all; as well as failing to document that the medication was given to the patient and therefore failing to charge the patient for the medication being issued.

Maintaining control over delivery of medications is critical to a well functioning health care facility, firstly to insure no harm comes the patients' health, to insure that no liability is incurred by the hospital which may arise in the event of a serious error in

delivery of medications, and lastly to provide tracking for billing purposes to insure proper cost recovery.

While the dispensing systems typically used today rely on procedural controls to avert errors, no procedural system is foolproof. Errors can and do occur regularly. Pilferage may also be a problem that is not easily dealt with by voluntary compliance with established procedural systems.

A similar critical relationship can exist in other settings where the proper association of an item with its intended use and/or recipient is essential. For example, in precision or mission critical machinery the use of a proper replacement part or proper accessory may be essential. For example, it may be essential that only a certain lubricant be used on a particular component of a particular model of jet engine, or that only a particular replacement part be used for that engine. While efforts are certainly undertaken to avoid mistakes, including printing labels with appropriate caution text -- errors can still occur with catastrophic results where, for example, a jet engine should fail due to fluid loss resulting from a leaking seal damaged by the use of an inappropriate and incompatible lubricant.

Accordingly, it is an object of the present invention to provide an apparatus which prevents errors from occurring during dispensing of pharmaceuticals to patients in a health care environment.

It is an object of the present invention to provide a bag, envelope, or other container on which or in which there is a unique description, picture, or illustration of the patient to receive the medication so as to allow the individual dispensing the medication to quickly verify that the correct patient is being given the medication contained in the container.

A further object of the present invention is to provide a bag, envelope, or other container on which or in which there is a unique color coding which is designed to help arrange the medications for dispensing in a certain order, by time to be dispensed, by day to be dispensed, or by shift to be dispensed to the patient.

Another object of the present invention is to provide a bag, envelope, or other container on which or in which there is a unique color coding, and symbols employed to

help distinguish among different types or classifications of medications which are being dispensed to the patient.

Yet another object is to provide a bag, envelope, or other container on which or in which there is a unique color coding to highlight special instructions pertaining to any of the items to be dispensed to the patient.

Another object is to provide a bag, envelope, or other container on which or in which there appears a bar code symbol, or other encoded machine readable information, identifying the individual who is the intended recipient of the contents of the bag, envelope or other container.

A still further object of the present invention is to provide a bag, envelope, or other container on which or in which there is a unique picture or illustration of an object associated with the contents of the bag, envelope or container so as to allow the individual opening the container to quickly verify that the contents of the container are being used only with the correct associated object.

These and other objects of the present invention will become apparent from the present disclosure and claims.

3. SUMMARY OF THE INVENTION

An apparatus is provided for containing medications to be dispensed to patients in a manner so as to minimize error. The apparatus comprises a container for holding medications to be dispensed to a patient and a label associated with the container. The label includes one or more data fields at least one of which includes a photographic likeness of the patient who is the intended recipient of the medications held in the container. In this manner the individual dispensing the medication is provided with a visual cue to permit the individual to compare the patient to whom the medication is being given with photographic likeness associated with the container in order to permit the individual to quickly and accurately verify that the medication is being given to the proper patient thereby preventing errors in the dispensing of medications to patients. In the preferred embodiment of the invention, the data fields include a machine readable data field comprising a bar code symbol which identifies the individual who is the intended recipient of the contents of the container. A data field is also provided which further includes a unique color code which is designed to help arrange the medications for dispensing in a certain order, by time to be dispensed, by day to be dispensed, or by shift to be dispensed to the patient. A further data field includes color coding and symbols to distinguish among different types or classifications of medications which are being dispensed to the patient. An additional data field includes a unique color coding to highlight special instructions pertaining to the items to be dispensed to the patient. Also provided is a data field including a human readable indication of the time of day when the contents of the container are to be dispensed to the patient.

The present apparatus is further provided with a perforation for facilitating opening of the container and a security bar code symbol affixed to the container overlying at least a portion of the perforation whereby the security bar code symbol is rendered unreadable upon opening of the container.

In one embodiment, the apparatus for dispensing medications to patients in a manner so as to minimize error comprises a camera for capturing a photographic image of the patient; means for electronically digitizing, storing, and accessing the image of

the patient; a source of flexible bags for containing medications to be dispensed to a patient; means for printing a label on the flexible bag where the label includes a photographic image of the patient whereby the individual dispensing the medication is provided with a visual cue to insure that the proper medication is given the intended patient; and means for sealing the flexible bag.

4. BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 of the drawings is a front elevational view of a preferred embodiment of the present invention formed from a flexible heat sealable plastic bag;

Fig. 2 of the drawings is a schematic diagram of the various main components of a system used to produce the present container apparatus; and

Fig. 3 of the drawings is a front elevational view of a unit dose package of a medication which may be used with the present invention.

5. DETAILED DESCRIPTION OF THE DRAWINGS

Fig. 1 is a front elevational view of the container for use in preventing errors in the dispensing of pharmaceuticals to patients in a health care environment, and in particular illustrating an array 11 of data that may be printed onto the medication container 10 for a particular patient. In an embodiment of the invention illustrated, the medication container 10 comprises a flexible heat-sealable bag for containing the medications to be dispensed to the patient and where the data array 11 is printed directly onto a bag. It is expressly deemed to be within the scope of the present invention to provide a medication container of another form, such as a rigid closeable container capable of receiving a label upon which the data array is printed.

Container 10 as shown, is a bag which may be formed from a roll of flexible plastic, clear or colored, bag stock 30. The bottom of container 10 is formed by a heat seal applied along line 31 which serves to close the bottom of the container. To form a closed container, a heat seal or glue line can be applied along line 32 to close the top of container 10 sealing the contents therein.

The data contained in the array may be readily tailored to the particular application. Likewise, the manner in which the data is presented may be readily tailored in that data may be presented in alpha-numeric form and may include means of color-coding or pattern-coding, visual images, and the like.

In the preferred embodiment, the data array 11 comprises several fields of data containing information that is required to ensure delivery of the prescribed medication to the proper patient at the proper time.

The field bearing reference numeral 12 contains a photographic image of the patient. The field bearing reference numeral 13 contains a bar-code symbol which conveys the patient's hospital assigned identification number. This bar code symbol serves to identify the patient and as further described herein may be used to record the time of date when the patient receives a particular medication. The field bearing reference numeral 14 contains information identifying the prescribed medication by name and quantity. Further confirming coding, such as the hours of the day such as 8, 12, 16 representing "zero hundred" on the 24 hour clock may be included to confirm

times at which the medications are to be dispensed. In the embodiment illustrated, an additional field 15 is provided for each field 14 which field contains instructions for administering the drug, such as the quantity and frequency of administration, and may contain as well additional instructions such as drug interaction information, etc. A further field bearing reference numeral 16 is shown and serves to convey special instructions to the individual dispensing the medication to the patient. In the example illustrated, the nurse is instructed to take the patient's pulse before administering the medication Digoxin and to take the patient's blood pressure before administering the medication Procardia-XL. It is further contemplated that the data appearing in fields 16 may be printed in a contrasting color, such as red, to the other data in array 11, such as black, so as to draw particular attention to the special information helping hospital personnel see the special instructions or warnings and further prevent mistakes from happening. A field bearing reference numeral 21 contains information in text format relative to when the medication is to be dispensed to patient, sometimes referred to as "medication pass" or "med pass" data. Fields bearing reference numerals 17 - 20 together serve to convey to the individual dispensing the medication "medical pass" information but in a color-coded and/or pattern-coded format. "Medical pass" information describes the time at which the medication contained in container 10 is to be administered to the patient. For example, the med pass field 21 may state "8:00 AM Med Pass", indicating that the medication is to be administered to the patient during the 8:00 AM medication rounds. Similarly, the med pass field may state "PRN", indicating that the medication is to be administered on an as-needed basis. For example, as opposed to being packaged for individual medication pass times, medications can be packaged for a given patient for an entire day or nursing shift with the multiple medications to be given over the designated period as called from on the printed information and indicia. Accordingly, other med pass information may reference such times as hour of day, day and date or nursing shift. It is also possible to generate an empty container 10 for such med pass times when no medication is to be dispensed to the patient.

In the example illustrated fields 17 - 20 are each illustrated as being the same color to signify the 8:00 AM med pass period. Each of the fields may be printed having other colors which are all the same, or differ to convey other established time periods for dispensing medications to patients. For example, fields 17 and 18 may be blue in color while fields 19 and 20 may be pink to signify a 6:00 PM med pass period. In another example, fields 17, 18 and 19 may be pink in color and field 20 black in color to signify the 9:00 PM med pass period.

Fields bearing reference numerals 22, 23 and 24 respectively are text fields providing the patient's name, hospital identification number, and room/bed number. The field bearing reference numeral 26 provides an indication as to the number of medication bags are to be opened for the particular medication pass time, and specifically indicates if multiple bags are called for.

As further shown in Fig. 1, the medication bag 10 may include a perforation 40 which is provided for ease of opening. The medication bag 10 may contain a second bar-code 41 that traverses perforation 40 and which may be used to detect tampering. In the event the perforation has been prematurely broken, the anti-tamper bar code will not be readable by a bar code scanner provided to track the dispensing of medications to patients and will serve to signal an alarm to indicate that possible tampering or theft of medication from the medication container 10 has occurred. The field bearing reference numeral 27 is shown comprising a unique symbol which may serve to provide a special indication as to the nature of the patient's condition, allergic cautions, or the nature of the medications in the bag. In the embodiment illustrated in Fig. 1, field 27 serves to indicate that controlled substance is packaged in medication container 10 thereby alerting hospital personnel that special handling may be required. Alternatively, field 27 may display a symbol indicating that one or more of the medications to be dispensed to the patient require refrigeration and accordingly are not included in container 10 but instead are to be retrieved from another location.

The properly filled and coded medication container 10 may thus be delivered to the patient and administered per the doctor's orders. As a further check for accuracy prior to administering the medication, the nurse or technician administering the

medication may use a portable scanner to read the bar codes from both field 13 on the medication packet 10 and the patient's wristband. If the bar codes do not match, the system can generate an audible and/or visual error signal. The scanner can also be used to scan the anti-tamper bar code 41 on the medication packet 10 to ensure that the packet has not been tampered with, and to ensure that no medication has been lost from or added to the packet in its trip from the pharmacy to the patient's bedside. If the perforated edge has been broken or tampered with, the anti-tamper bar code will be unreadable and an error signal will be generated.

The data array 11 contains a variety of information which provides visual error detection means to ensure that the proper patient gets the proper medication at the proper time. The textual patient identification fields 22 and 24 indicate patient name and room number, helping to ensure the medication reaches the proper patient. The medical pass field 21 and color code fields 17 through 20 correspond to a particular medical pass made at a particular time of day, helping to ensure that the medication is administered on the proper schedule. The organization and appearance of the graphics, text, images printed on the bag, container or label may vary from that depicted in the attached Fig. 1 and still be within the scope of the present invention.

It is contemplated that the portable scanner may be linked to and may download information to a main system computer. The main system computer may then track the order, issue, and administration of the patient's medication. The system data may also be accessed for billing purposes. At the end of a patient's hospital stay or at the end of a billing period for an extended stay, the system's data may be used to generate billing information for medications administered while in the hospital.

Other embodiments of the present invention are contemplated for use in non-medical environments. For example, in a package delivery or "coat check" setting it may be critical for security reasons that a given item be delivered to, or be permitted to be claimed by, only a specific person. For example when checking expensive fur coats a coat check facility can electronically take the photograph of the person checking the coat. The image can be printed directly on the coat check claim receipt given the coats owner with a copy of the image retained in a computer. When the coat is claimed the

owner can present the claim receipt bearing the owner's picture. The operator of the facility can compare the image on the coat check receipt with the person presenting the receipt to determining whether the true owner is claiming the coat -- thereby preventing the coat from being given to the wrong person.

In another setting, it may be critical that a given component only be used in maintaining a particular piece of machinery where incorrect application may result in damage to the machine. For example, it may be that a given nut or bolt or lubricant is to be used only on a particular model of jet engine where use of the wrong nut, bolt or lubricant will damage the jet engine in use, possibly causing the engine to fail and a plane to crash with potentially catastrophic results. The image appearing in field 12 can be that of the engine, or component thereof, which uniquely identifies the part packaged in the container 10 with the intended recipient object.

In such application, the graphics, text and bar-coding printed on the bag or container as a data array and the information contained therein may be tailored for any particular application. For example, the invention may be used to control the issue and installation of equipment or machine parts to preclude use of inappropriate parts, lubricants, gaskets, solvents, etc. on a particular piece of equipment. Rather than containing medical information, the data array in this type of application might include fields for equipment number, equipment type, a visual image of the equipment, a description of the part, critical information regarding its use or installation, etc.

One embodiment of the present invention is designed to function in connection with a computerized system designed for cross-checking the proper administration of the medications, as well as to detect tampering, wherein bar-codes, bar-code scanners and visual photographic images are used to permit the individual dispensing the medication to correlate patients to their medical charts, and more importantly, to the actual medications dispensed to the patient at the time they are dispensed.

In the computerized system contemplated, upon admission to a hospital, each patient is typically assigned a unique identification number which is encoded as a bar code on the patients chart, wrist band and other hospital records. An appropriate system printer prints a patient identification tag containing the patient's bar-code

identification and other text-based identification information, such as patient name or hospital identification number. The identification tag may be attached to the patient by means of a conventional hospital wristband. The printer also prints a bar code label for application to the patient's chart. Alternatively, the printer may also print the complete patient chart itself upon which is integrated the patient identification information, including the bar code. In a preferred embodiment of the invention, conventional video capture equipment, such as a digital camera connected to a personal computer, is used to obtain a digitized photographic image of the patient. The digitized image is correlated to the patient's unique identification bar-code. The bar-code and digitized image are stored in system memory for future use.

After a doctor has prescribed medication for a patient, and has duly noted the prescription on the patient's chart, an appropriate hospital individual enters this information into the system computer. The computer software then periodically and automatically generates medication orders for use by the hospital pharmacy. The medication orders are automatically electronically received at the pharmacy so that the pharmacist or other hospital technician may fill the doctor's medication orders. The pharmacist using a computer monitor is prompted to select and collect the various medications on a patient-by-patient basis toward filling the medication carts used in the hospital. The pharmacist places the prescribed medication into a suitable container which is labeled with patient identification information and pertinent information relating to the medication and its administration. The carts may be filled with sufficient medication to last a given period of time, such as a full nursing shift.

The pharmacy component of the dispensing system specifically comprises a computer terminal, a source of flexible bags or other containers, a bar code scanner, a printer, and sealing apparatus to seal the bags containing the dispensed medication.

In one embodiment, when the system computer generates a medication order, the order is electronically transmitted to the pharmacy's computer terminal. The pharmacy system including the computer terminal, bag dispenser, printer, scanner, and bag sealers is used to perform the following operation.

As each individual order appears on the pharmacy's computer terminal identifying the patient and indicating the required medication, a bag is advanced from the bag dispenser and fed to the printer. The printer in turn prints directly on the bag information and indicia in graphic, text and bar-code format. (In place of a bag, an envelope or other tube stock feedable material or other container suitable for holding the prescribed medications may be used.) Alternatively, it is contemplated that the printer may print such identifying information on a label which may in turn be affixed to a different form of container suitable for holding the particular medication, or a separate container for holding medications which require refrigeration or other special handling, such as narcotics which may be kept under lock and key. In the preferred embodiment of the invention at a minimum the patient's identification bar-code and a photographic image of the patient is printed on the bag.

The bag then passes to the scanner which electronically reads the bar-code printed on the bag which corresponds to the patient's unique identification. The scanner thereby confirms the proper identity of the patient for whom medications are to be collected by the pharmacist or technician. Alternatively, using a hand held bar-code scanner, the pharmacist may manually scan the bar code printed onto the container if a separate type container is used or as a check to ensure that the bar code was properly printed. In the event the bar code printed onto the bag does not correspond to the patient's correct bar code, the system will generate an audible and/or visual error signal.

The bag is then advanced to a point where one end is opened ready to accept filling with the appropriate medications as prompted by the computer terminal. To fill the medication order, the pharmacist reads the prescription information from the adjoining computer terminal and selects the corresponding medication from the pharmacy's stock.

In some hospitals, unit dose pre-packaging medications are used. For example, aspirin and other tablets may be packaged individually in flexible clear plastic bags as single 200MG tablets. On the unit dose bag appears a label containing a bar-code uniquely identifying the medication packaged therein, together with human readable

text also identifying the packaged medication. Alternatively instead of printing on the bag a paper card may be printed and inserted into a clear bag or other container.

In a hospital incorporating pre-packaged unit dose medications bar-coded for identification the procedure is as follows. The pharmacist scans a bar-code symbol on a medication tray signaling the computer system that the particular patient's medications are being placed in the particular tray. The computer prompts the pharmacist to select the unit dose medications one-by-one. The pharmacist as prompted by the computer terminal selects the prescribed medications in turn and in turn scans each selected unit dose package with a bar-code scanner to thereby signal the computer that a given medication has been selected and placed in the medication tray. If for example the computer calls for two 200MG aspirin and the pharmacist selects only one pre-packaged tablet the computer screen will register that only a single tablet has been scanned and will prompt the pharmacist to select an additional pre-packaged unit dose tablet. If the pharmacist selects an incorrect medication, such as 350MG tablet instead of the 250MG tablet ordered by the doctor the system will generate an audible and/or visual error signal, notifying the pharmacist of the error when the individual unit dose package is scanned before being put into the bag. Accordingly, when the initial phase of filling the medication tray is complete the computer system assures the proper medications have been selected.

If the pharmacist or technician is collecting medications from conventional bulk or bottle storage, as opposed to unit dose storage, the pharmacist can scan the bar code on the medication's bulk container from which individual tablets and the like must be dispensed. Once the pharmacist has selected the proper medication container, he/she dispenses the required number of pills, capsules, etc. into the bag or envelope. As a check for accuracy, the pharmacist may manually key into the system the number of units of medication actually dispensed from the bulk container. If the pharmacist keys in a number that does not correspond to the value (required number of units) prompted by the system, the system will generate an audible and/or visual error signal.

When all of the required medication has been placed into the bag, the bag is sealed by heat, adhesive, or other conventional means. As a further check of

accuracy, and to inhibit tampering and pilferage, the filled bag may be placed on an electronic scale which interfaces with the computer system. The computer system may compare the actual weight of the bag with a calculated weight which is a function of the medications called for, plus the weight of the bag. If the actual and calculated weights do not compare within an acceptable deviation, the system will generate an audible and/or visual error signal.

Once the trays are filled the medication carts/cassettes are transported to the nursing station or otherwise taken directly to the hospital floor for delivery of medications to the patients.

When called for by the doctor's orders a nurse, for example, may begin dispensing medications to the patients under the nurse's care. The medication cart may be rolled down the hospital floor and individual trays accessed from immediately outside of each patient's room, or the trays removed from a stationary cart storage position and walked down to each patient's room.

Upon entering the patient's room the nurse may follow standard hospital protocol and check the patient's chart listing the prescribed medications and time for delivery against the contents of the medication tray. Rather than rely merely upon the patient's chart, the patient's wrist band id, a posted name card, or the nurse's memory, the present invention offers the added benefit of including upon the medication bag a printed photographic image of the patient thereby providing an immediate visual cue to insure proper administration of the medication and the intended recipient. For example, if the photograph pictured on the medication bag is that of male child and the patient in the bed to whom the nurse is about to dispense medication is an adult or a female, the nurse will have an immediate indication that that something is amiss and to abort dispensing the medication whereby a potentially fatal error is avoided. Further, upon viewing the other visual cues printed on the medication bag other errors may be avoided. For example, if the nurse is dispensing medications for the noon "medication pass" the predetermined color code signaling noon medications will appear on the bag containing the medications to be given at noon. If the wrong bag is selected from the tray, for example a bag bearing a color code corresponding to a 6:00 p.m. med pass,

the nurse is provided a further color cue that again something is amiss and that the dispensing is to be aborted. Additionally, if medications remain in the tray with "expired" color codes the nurse can easily notice that an error has been made and corrective action may be taken.

In a more advanced application of the present invention dispensing medications may occur as follows. When the nurse, for example, desires to deliver a medication to a patient a portable bar-code scanner with internal memory may be used. Specifically, the nurse removes the medication tray from the cart and scans the bar code on the tray as well as a bar-code appearing on the nurses hospital identification badge. The nurse then enters the patient's room and scans the patients chart and more importantly the patients wrist band. By means of the pre-loading of information into the portable bar-code scanner, which pre-loading occurs at a designated data-transfer station, the bar-code scanner is able to compare the identification of the tray to the patient and signal an alarm if the patient and the medication tray do not match.

The nurse may then remove the bag containing the pre-packaged unit dose medications from the tray and according to the doctor's orders delivers the medication to the patient. However, before opening the bag and again each package the bar-code on the package is scanned. Again, by means of pre-loaded data, the bar code scanner, using stored data and its internal clock, is able to signal an alarm if the nurse were to scan a medication not prescribed for the patient, or fails to scan and thus deliver all of the medications prescribed for delivery at the appointed time.

The bar-code scanner thus has data stored and updated therein verifying that a particular nurse delivered particular medications to a particular patient at a particular time. Such data can thereafter be transferred back to a central computer at a data transfer station to update patient medication administration records and accounting/billing records.

In the simplest embodiment, the present invention may take the form of a bag or other container for holding the various loose medications to be given to the patient and a printed label containing a photographic image of the patient who is to receive the medications. The label may be printed directly on the bag or on a separate card which

is inserted loose in the bag and visible therethrough. The individual delivering the medications is thereby able to compare the photographic image to the patient in the hospital bed to confirm that the medications are being given to the correct patient.

Fig. 2 of the drawings is a schematic diagram of the various main components of a system 100 used to produce the present container apparatus. In the contemplated system medications are stored on shelves or peg board racks represented by reference number 101. The system for packaging medications operates under the control of a computer system represented by terminal 107. System 100 includes a source 102 of bag stock 108. As it is needed, bag stock 108 is released from roll 108 and passes over printer 103. As described herein, printer 103 serves to print the various data fields directly on bag stock 108. The bar code printed on the bag stock 108 by printer 103 is read by bar code reader 104 which prompts the pharmacist to assemble and package the various medications into the container formed from bag stock 108. Sealer 105 applies a heat seal to the end of the bag stock to form the bottom seal of the container for holding the medications and serves to create a perforation at the tope of the bag to permit the bag to be opened for filling. The bag stock is then advanced such that the open top is now accessible and such that the bag container is able to be filled. As prompted by computer terminal 107, the pharmacist retrieves from medication storage 101 the various unit dose medications and places them in the open bag. When computer terminal 107 signals that the bag is filled with the necessary medications the bag is moved to sealer 106 which seals the top of the container.

Fig. 3 of the drawings is a front illustration of a typical unit dose package. In the example illustrated, a single 250 milligram tablet of aspirin 112 is shown packaged in a clear plastic bag 110 on which is printed bar code 111 containing the electronically readable identification of the contents and legend 113 comprising the human readable indication of the bag's contents. A hole 114 is provided for permitting the unit dose package to be held on a vertical peg-board type rack. Perforation 115 assists the user in opening the container.

In its more complex embodiment, the present invention may take the form of a component of a computer driven medication handling and dispensing system operating

under the control of various software modules. For example, software will command the sending of information to a printer capable of printing onto a bag, envelope, or other container, or onto a filling slip placed loose in the bag, envelope or container the individual's color picture, quantities, directions, color codes, and bar-codes applicable to the recipient and contents.

A software module allows filling of the items, parts, medicines, etc. in a way that will warn the employee visually, and audibly if an incorrect item is being introduced into the container. The software will keep track of all items which are introduced into the container not just by the individual item number but also by a unique specific consecutive numbering system so that precise tracking of each exact item is known to be in each container. Through this method it will be known, for example, not only that "Aspirin 325 mg." manufactured by XYZ company was put into "Container #1" but also where that aspirin traveled in the hospital from the dispensing area all the way to the end user, or patient. Software will sort and direct the printer to print on the container or a filling slip all of the information, as shown in the drawings, by each hour, or by each shift, or by each day; and by each customer or patient. Software can further be able to keep track of the internal tracking number of each drug or item to make sure each precise item given to the end user is the same precise item sent out in the filled container for each patient. The software will further be able to check the employee who is giving each item to precise moment for "Controlled" items, or for any items, or for all items if desired by scanning the second bar-code on the package in the area of the perforation. In such case Container 10 will have a special bar-code 41 in the vertical perforation area 40 for certain items, such as narcotics. The employee will scan the patient bar-code 13 first, followed by scanning the special extra bar-code 41. The bar-code 41 will be torn apart once as the container 11 is opened. This bar-code will not have human readable information under it. The purpose is to force the employee to scan the client identification bar-code 13 under the client's picture 12 first, and then scan the bar-code 41 in the perforation area. If the employee has scanned both of these bar-codes, there will be very good proof of who opened the container, and at what time. This accountability will virtually eliminate pilferage. The exact times of the

scan of the client bar-code on the container 10, bar-code 41 on the perforation area 40, the scan of the wrist band, and the scan of the medications must be close together. If not, the software will show discrepancies in time, which could lead to catching employees who may not doing their job correctly, or attempting to steal the items. This second bar-code 41 on the container perforation area 40 may be used only for "Control Drugs" or highly controlled or valuable items.

The foregoing description and drawings merely explain and illustrate the invention and the invention is not limited thereto except insofar as the appended claims are so limited, as those skilled in the art who have the disclosure before them will be able to make modifications and variations therein without departing from the scope of the invention.

Claims

1. An apparatus for containing medications to be dispensed medications to patients in a manner so as to minimize error, said apparatus comprising:
 - a container for holding medications to be dispensed to a patient;
 - a label associated with the container, the label including one or more data fields including at least a photographic likeness of the patient who is the intended recipient of the medications held in the container,
 - whereby the individual dispensing the medication is provided with a visual cue to permit the individual to compare the patient to whom the medication is being given with photographic likeness associated with the container in order to permit the individual to quickly and accurately verify that the medication is being given to the proper patient thereby preventing errors in the dispensing of medications to patients.
2. The invention according to Claim 1 wherein the data fields further include a machine readable data field comprising a bar code symbol which identifies the individual who is the intended recipient of the contents of the container.
3. The invention according to Claim 1 wherein the data fields further include a unique color code which is designed to help arrange the medications for dispensing in a certain order, by time to be dispensed, by day to be dispensed, or by shift to be dispensed to the patient.
4. The invention according to Claim 1 wherein the data fields further include color coding and symbol to distinguish among different types or classifications of medications which are being dispensed to the patient.
5. The invention according to Claim 1 wherein the data fields further include a unique color coding to highlight special instructions pertaining to the items to be dispensed to the patient.

6. The invention according to Claim 1 wherein the container further includes a perforation for facilitating opening of the container and a security bar code symbol affixed to the container overlying at least a portion of the perforation whereby the security bar code symbol is rendered unreadable upon opening of the container.

7. The invention according to Claim 1 wherein the data fields further include a human readable indication of the time of day when the contents of the container are to be dispensed to the patient.

8. An apparatus for dispensing medications to patients in a manner so as to minimize error, said apparatus comprising:

- a camera for capturing a photographic image of the patient;
- means for electronically digitizing, storing, and accessing the image of the patient;
- flexible bag for containing medications to be dispensed to a patient;
- means for printing a label on the flexible bag, the label including a photographic image of the patient whereby the individual dispensing the medication is provided with a visual cue to insure that the proper medication is given the intended patient;
- means for sealing the flexible bag.

9. An apparatus for containing items which are to be used solely in connection with certain objects and not with certain other objects in a manner so as to minimize error in use, said apparatus comprising:

- a container for holding items to be used only with certain objects;
- a label associated with the container, the label including one or more data fields including at least a photographic likeness of the object with which the item held in the container is to be used,

- whereby the individual using the item in the container is provided with a visual cue to permit the individual to compare the object with which the item is to be used with photographic likeness of the object associated with the container in order to permit the individual to quickly and accurately verify that the item is being used in connection with the proper object thereby preventing errors in the use of the item.

1 / 2

32

21

20

19

17

18

8:00 AM
Med Pass

11

26

Envelope
1 of 1

27

III

41

12

40

22

1 1 2 3 4 7 5

13

23

Smith, Mary

Patient #:1123475

Room 101A

24

25

1-Aspirin 5 GR.(TID) ~ 14
Take tablet 3 times a day. ~ 15

1-Colace/DSS 100 MG Capsule (BID)
Take 1 capsule 2 times a day.

1-Digoxin 0.25MG Tablet
Take 1 tablet in morning.
Take pulse before giving. ~ 16

1-Mellaril/Thioridazine 25 MG Tablet
Take 1 tablet 2 times a day.

1-Nitro-Dur Patch 5.0 MG
Apply 1 patch daily in the morning

1-Procardia-XL 30 MG Capsule
Take 1 capsule in the morning for hypertension.
Take blood pressure before giving. ~ 16

30

31

10

FIG. 1

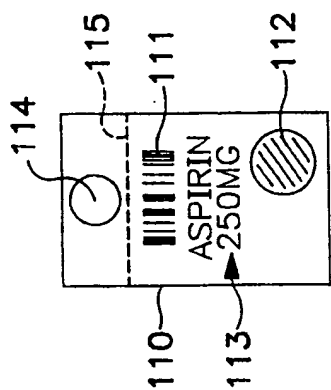


FIG. 3

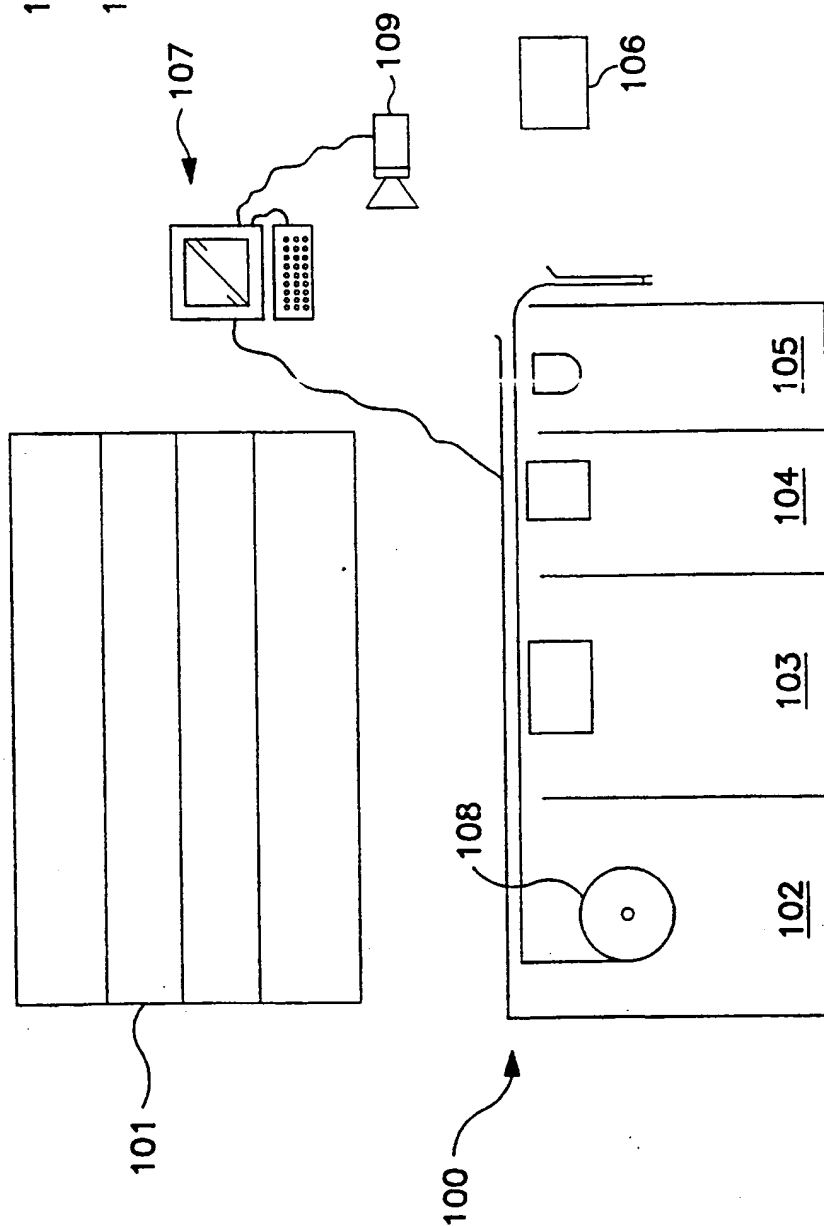


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/20550

A. CLASSIFICATION OF SUBJECT MATTER .

IPC(6) :G06F 17/00; A61J 1/00

US CL :364/479.01; 206/534

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 364/479.01,479.05,478.13,478.15; 383/5,106,37,207;414/273;53/411;206/534;283/900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,390,796 A (KERFOOT, JR.) 21 February 1995, col. 2, lines 29-34; col. 4, lines 3-12; col. 5, lines 1-16; col. 5, lines 28-38; and the figures.	1-9
Y	US 5,064,071 A (KERFOOT, JR.) 12 November 1991, col. 1, lines 33-37; col. 2, lines 16-21; col. 2, lines 29-37; col. 3, lines 39-43; col. 4, lines 34-41; and the figures.	1-9
Y	US 5,597,995 A (WILLIAMS et al.) 28 January 1997, col. 4, lines 37-44 and the figures.	8
Y	US 5,593,267 A (MCDONALD et al.) 14 January 1997, col. 4, lines 48-65; col. 5, lines 4-13; and figure 2.	8

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 29 DECEMBER 1998	Date of mailing of the international search report 22 FEB 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer STEVEN R. GARLAND <i>Joni Hill</i> Telephone No. (703) 305-3900

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/20550

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,972,657A (MCKEE) 27 November 1990, col. 6, line 53 to col. 7, line 19; and the figures.	2-5,7
Y	US 4,483,018A (WHELAN) 13 November 1984, col. 6, lines 60-63; col. 7, lines 15-33; and the figures.	6